Legislative Analysis

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NEWBORN SCREENING QUALITY ASSURANCE ADVISORY COMMITTEE

Senate Bill 794 as passed by the Senate
Sponsor: Sen. Tom George
House Committee: Health Policy
Senate Committee: Health Policy

First Analysis (1-30-06)

BRIEF SUMMARY: The bill would create the Newborn Screening Quality Assurance Advisory Committee; require the committee to review the list of newborn screening tests and make recommendations on additions or deletions to the list; and allow the Department of Community Health to approve or reject the recommendations and the legislature to approve the recommendations by concurrent resolution.

FISCAL IMPACT: The bill could result in a modest cost increase to the state as discussed later in more detail in the analysis.

THE APPARENT PROBLEM:

The Public Health Code requires all newborn infants to be tested for eight specific metabolic diseases that cause mental or physical impairment (or death), as well as for other treatable but otherwise disabling conditions as designated by the Department of Community Health. A base price for the battery of tests is set by statute, but is adjusted annually to reflect inflation. Legislation is needed whenever the department feels that scientific evidence supports the addition of another disease or metabolic disorder to the list and as needed to increase the base testing price if program costs exceed inflationary increases.

Newborn screening capabilities continue to evolve; now, a decision to add to or delete from the list of required tests involves analyzing complicated scientific evidence. Due to the increasingly technical nature of reviewing the scientific literature, some believe that the decisions regarding which medical conditions should be tested for at birth should be entrusted to those with medical expertise. Legislation has therefore been offered to change the process by which the list of required newborn screening tests are altered.

THE CONTENT OF THE BILL:

The bill would add a new section to the Public Health Code to create the Newborn Screening Quality Assurance Advisory Committee within the Department of Community Health. The bill would do the following:

- Create a 10-member committee composed of individuals representing Blue Cross Blue Shield of Michigan, hospitals, physicians, HMOs, the Department of

Community Health's Public Health Administration and Medical Services Administration, the general public, and a neonatologist with experience and background in newborn screening.

- Require the committee to meet annually to review the list of newborn screening tests required under the code and departmental rules, regulations, and guidelines.

- Require the committee to annually submit a written report to the DCH regarding the appropriateness of the existing list of required tests and make recommendations to include additional screening tests that are nationally recognized in scientific literature or national standards for conditions that can be ameliorated or treated if identified and to remove tests that are no longer supported.

- Conduct a financial review of recommended changes to the list of newborn screening tests. The annual written report would have to include a recommendation for increasing or decreasing the amount charged for the tests under Section 5431 of the code. A recommended change could not exceed any net change in the amount of the actual cost of any proposed additional tests and follow-up minus savings from any proposed deleted tests and follow-up.

- Within 30 days of receiving the annual written report, allow the DCH to approve or reject the recommendations of the committee. If the recommendations are not rejected, or if the DCH failed to act within the 30-day time frame, the recommendations would have to be forwarded to the legislative committees of the House and Senate having oversight of public health issues for approval.

- Allow the legislature 45 days to approve or reject the recommendations. The standing committees of the House and Senate with oversight of public health issues would have to adopt the recommendations by concurrent resolution. Each chamber would then have to approve or reject the recommendations, without amendment, by recorded vote. If the recommendations were not rejected within the 45-day period, the recommendations would be considered to be approved, would have to be adopted by the DCH, and would take effect six months later. The 45-day time period would have to begin on the first legislative session day after the recommendations had been received and would have to include at least nine session days.

- Require health professionals and health facilities to report to the DCH the results of all hearing tests and screens conducted on infants less than 12 months of age and on children less than three years of age who had been diagnosed with hearing loss. The report would be on a department-prescribed form and would have to include the type, degree, and symmetry of the diagnosis, along with where and when the diagnosis had been made.

MCL 333.5430 and 333.5432

FISCAL INFORMATION:

Senate Bill 794, as passed by the Senate, amends the Public Health Code to create a 10-member Newborn Screening Quality Assurance Advisory Committee empowered to initiate revisions to the list of required newborn genetic disease screening tests, and to propose a fee change based on the revisions. The revisions would take effect unless disapproved by DCH or by the House or Senate standing committees on public health policy.

The proposed changes would replace the current process that necessitates statutory change to revise the base fee.

This program was established in 1965 and currently functions with the assistance of an advisory committee that serves a technical consulting role, which will continue to be needed for program support. There may be modest costs to implement the bill especially in the first year; however, the essential structure to support the new committee's activities should currently be in place. Current statutory language would be retained which allows the fee to be adjusted annually to reflect the cumulative annual percentage change in the Detroit consumer price index. The current fee for a single test card that covers all newborn screening tests is $56.83, based on the statutory fee of $53.71 with recent annual inflationary adjustments.

About 128,000 children are born in Michigan each year. In 2004, 192 infants were identified through this testing as having one of the treatable conditions, and treatment was commenced, helping to prevent or reduce the consequences and costs of these genetic disorders. The successes of the program help to reduce the need for higher levels of services for these children that might be provided through special education, children's special health care services, and Medicaid.

The bill's requirement for reporting if a newborn hearing test is administered may have modest cost implications as well, for recording and retention of the data.

ARGUMENTS:

For:

Since 1965, when legislation mandated all newborns to be tested for phenylketonuria (PKU), a rare disorder that can cause severe, irreversible brain damage, the Public Health Code has required certain tests of all newborns. Currently, screening is conducted for eight specific rare, but potentially devastating, metabolic diseases and the Department of Community Health has the authority to require testing for other treatable but otherwise disabling conditions.

Each time the medical community feels that scientific evidence supports the addition of certain types of screening tests, it requires amending the Public Health Code via the bill process, a process that can be lengthy, especially if the bill fails to complete the process within the time frame of a two-year legislative cycle and needs to be reintroduced in a subsequent cycle.

The bill would instead create a committee of experts that would have the responsibility of reviewing the scientific literature and making annual recommendations to the Department of Community Health regarding the appropriateness and advisability of diseases and conditions to be on the list. The DCH would have authority to approve or reject the recommendations. If the department approved the recommendations or failed to act within the bill's time frame of 30 days, the matter would go before the legislative committees of the House and Senate with oversight of public health issues. The legislature would then have 45 days to approve or reject the recommendations by concurrent resolution instead of a bill. If the recommendations were not rejected by the legislature before the end of the 45-day period, they would go into effect six months later. This would greatly streamline the process for adjusting the required screenings and would enable the state to more rapidly incorporate cutting edge research.

For:

According to information supplied by the Department of Community Health, early detection of hereditary and congenital disorders, along with appropriate treatment and follow-up, has become a cost-effective public health initiative that prevents mental retardation, death, or disability. However, because the targeted disorders can cause damage early on, and because many of these children appear normal at birth, it is imperative that all children be tested shortly after birth. It is also important to ensure that newborn screening be universal across the state and that all children identified with a disorder receive appropriate follow-up care.

Currently, all Michigan newborns are tested for 11 disorders through the Newborn Screening Program. In 2004, 192 infants were identified with one of the specified disorders and treatment was commenced. The DCH has been testing a pilot program in some areas of the state that screens for 41 disorders. If the state were to fully implement available testing technology and expand the number of screens to 41 statewide, more infants with deadly or disabling disorders could be identified and successfully treated.

Though increasing the number of conditions screened for would result in some additional costs to the state, early detection and treatment could also result in significant savings to the state in regards to reducing or eliminating the need for state-supported services such as special education services and Medicaid benefits. For example, the medical care for a child born with glutaric acidemia, Type 1, a disorder that causes brain damage but that could be tested for, can easily exceed half a million dollars in less than three years, according to information supplied by the March of Dimes. Identified early, the disorder can be successfully treated by dietary changes, allowing the child to develop normally.

Furthermore, a recently released report by the American College of Medical Genetics to the U.S. Department of Health and Human Services Bureau of Maternal and Child Health identified 29 primary conditions and 25 secondary conditions that should be part of each state's screening program, along with hearing screenings. Of the seven states in HRSA

Region 4, Michigan is the only state that has not yet implemented these recommended screenings. Enactment of the bill will enable Michigan to incorporate scientific findings and to review and adopt national recommendations into its newborn screening program in a timely manner.

Against:

It would seem that physicians would recommend those screening tests deemed necessary to the parents, and that parents could request that their newborns be screened for these debilitating disorders, rather than having to put this into statute with legislative oversight.

Response:

Physicians need a medical reason, such as family history of a disorder or observable symptoms, in order to support ordering medical tests. The metabolic disorders recommended for routine newborn screenings are for conditions that are so rare that most physicians and parents would not be aware to request testing. In addition, most of these conditions do not present with symptoms until months later, and then only after permanent damage has occurred. Yet, early treatment can prevent severe disabilities and death. For that reason, newborn screening is viewed as being a public health issue and therefore should continue to be overseen by both the executive and legislative branches of government. Because these disorders have such a severe impact on a child's development, it is imperative that all conditions found to be able to be identified through early testing and for which early treatment is known to minimize or eliminate death or disability should be included in newborn screening programs. The bill would further this goal and improve the health and well-being of the state's children.

POSITIONS:

The Department of Community Health supports the bill. (1-24-06)

A representative of the Michigan Health & Hospital Association testified in support of the bill. (1-24-06)

A representative of Michigan's Children indicated support for the bill. (1-24-06)

A representative of the Michigan Association of Health Plans indicated support for the bill. (1-24-06)

A representative of Ascension Health indicated support for the bill. (1-24-06)

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